

§ 161.20

AUTHORITY: 7 U.S.C. 136–136y.

SOURCE: 49 FR 42881, Oct. 24, 1984, unless otherwise noted. Redesignated at 72 FR 60253, Oct. 24, 2007.

Subpart A—General Provisions

SOURCE: 49 FR 42881, Oct. 24, 1984, unless otherwise noted. Redesignated and amended at 72 FR 60253, 60254, Oct. 24, 2007.

§ 161.20 Overview.

(a) *Legal authority.* These requirements are promulgated under the authority of sections 3, 5, 12, and 25 of the Federal Insecticide, Fungicide and Rodenticide Act, as amended (FIFRA) (7 U.S.C. 136–136y).

(b) *Purposes of this part.* (1) The primary purpose of this part is to specify the types and minimum amounts of data and information the Agency requires in order to make regulatory judgments about the risks and benefits of various kinds of pesticide products under the criteria set forth in FIFRA sections 3(c)(5) (C) and (D) and 3(c)(7).

(2) This part also specifies the types and minimum amounts of data and information the Agency requires to decide whether to approve applications for experimental use permits under FIFRA section 5.

(3) Finally, this part specifies the types and minimum amounts of data and information that an applicant for registration, amended registration, or reregistration must submit or cite in support of an application in order to satisfy the requirements of FIFRA section 3(c)(1)(D) and sections 3(c)(5)(B) or 3(c)(7). Use of the term “registration” in this part will pertain to new registrations and amended registrations as well as reregistration accomplished under section 3(g), unless stated otherwise.

(c) *Availability of related guidelines.* The data requirements for pesticide registration specified in this part pertain to product chemistry, residue chemistry, environmental fate, toxicology, reentry protection, aerial drift evaluation, wildlife and aquatic organisms, plant protection, nontarget insects, product performance, and biochemical and microbial pesticides. The standards for conducting acceptable tests, guidance on evaluation and re-

40 CFR Ch. I (7–1–10 Edition)

porting of data, further guidance on when data are required, definition of most terms, and examples of protocols are not specified in this part. This information is available in advisory documents (collectively referred to as Pesticide Assessment Guidelines) through the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (telephone: 703-487-4650).

§ 161.25 Applicability of data requirements.

(a) Some kinds of data and information are specified in subparts C and D of this part as “required” (“R”) for the evaluation of some or all types of products. Other kinds of data and information are specified in those sections as “conditionally required” (“CR”), that is, they are required if the product’s proposed pattern of use, results of other tests, or other pertinent factors meet the criteria specified in those sections. The terms “required” and “conditionally required” are further discussed in §§ 161.100 and 161.101.

(b) The Agency recognizes that certain data requirements may not be applicable to (or should be waived for) some products, and has made provisions for such cases in this part as specified in § 161.35 *Flexibility of the data requirements*, § 161.40 *Consultation with the Agency*, § 161.45 *Waivers*, and § 161.60 *Minor uses*.

[49 FR 42881, Oct. 24, 1984, as amended at 53 FR 15999, May 4, 1988]

§ 161.30 Timing of the imposition of data requirements.

This part establishes requirements for the types of data which are necessary to support the unconditional registration of a pesticide product under section 3(c)(5) of the Act. While every registered pesticide product must eventually be supported by the data required by part 161, when an applicant or registrant must initially satisfy these data requirements depends on the factors listed below in this section.

(a) *Existing Registrations.* A registrant of a currently registered pesticide product is not obligated to satisfy any data requirement in part 161 with respect to that product until he receives a notice under section 3(c)(2)(B) of the